

Message

---

**From:** Miller, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA0582F5BA6540C687844F9289A4F74F-DAVID J. MILLER]  
**Sent:** 11/25/2020 3:10:19 PM  
**To:** DavidJ Miller [Miller.DavidJ@epa.gov]  
**Subject:** FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]  
**Attachments:** CCPR52 DRAFT Schedules and Priority Lists 12102019.xlsx

---

**From:** Miller, David  
**Sent:** Monday, November 04, 2019 6:37 PM  
**To:** Doherty, Michael <Doherty.Michael@epa.gov>  
**Cc:** Niman, Aaron (niman.aaron@epa.gov) <niman.aaron@epa.gov>  
**Subject:** FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

FYI- I think that this (moving from 2020 to 2021) was probably a given. It's just unfortunate it was done with what I believe is misinformation. What's good is that at least aldicarb is no longer taking a spot.

I am pretty sure Karina is entirely clueless on the backstory or that Dr. Hodges would need to -- but has to date not formally requested of EPA -- this release. And Karina probably also believes that the request from Larry was indeed "to allow enough time for the EPA to submit the studies to the CCPR". Likely, too, she believes that this is something that EPA is now working diligently on, ignorant of the fact that to date Larry has not submitted a formal FOIA request that EPA release or otherwise submit these Bayer-owned studies to CCPR.

David

---

**From:** Budd, Karina <Karina.Budd@agriculture.gov.au>  
**Sent:** Monday, November 04, 2019 4:08 PM  
**To:** Larry Hodges <larryhodges@meycorp.com>  
**Cc:** Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; IMCEAMAILTO-Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com; Furlow, Calvin <Furlow.Calvin@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; antoinepuech@meycorp.com  
**Subject:** FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Dear Larry,

Ian Reichstein is on extended leave and I am managing the CCPR Priorities working group. Regarding this schedule, aldicarb has been moved from the 2020 periodic review to the 2021 periodic review (see attached).

Aldicarb was not included in the recent JMPR data call in for JMPR review in 2020:  
[http://www.fao.org/fileadmin/templates/agphome/documents/Pests\\_Pesticides/JMPR/2020\\_Call\\_for\\_data\\_Final.pdf](http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/2020_Call_for_data_Final.pdf)

I encourage you to join the CCPR-Priorities-2019 electronic working group (EWG), where updated priority and schedule documents will be loaded.

The EWG platform link is at: <http://forum.codex-alimentarius.net/index.php>  
You will need to register for the online platform: <http://forum.codex-alimentarius.net/viewtopic.php?f=13&t=110>

The Priorities EWG is titled "*Establishment of CCPR schedules and priority list for the evaluation of pesticides by JMPR*".

The online invitation to this forum is at  
[http://www.fao.org/fileadmin/user\\_upload/codexalimentarius/invitations/Australia-CCPR-EWG%20PL%20invitation%202019.pdf](http://www.fao.org/fileadmin/user_upload/codexalimentarius/invitations/Australia-CCPR-EWG%20PL%20invitation%202019.pdf)

If you have any problems with this process, there are videos  
(<https://www.youtube.com/watch?v=EJn9k7wNSwk&feature=youtu.be>) and your national Codex contact point should be able to provide assistance.

Thankyou for following up with us, and I look forward to further updates closer to the next meeting of CCPR.

Kind regards,

*Karina Budd*

Karina Budd  
Director - Residue Chemistry and Laboratory Performance Evaluation Section  
National Residue Survey | Exports Division | Department of Agriculture  
Phone +61 2 6272 5795 | Mobile +61 408 695 904 |  
Email [karina.budd@agriculture.gov.au](mailto:karina.budd@agriculture.gov.au)  
18 Marcus Clarke Street, Canberra ACT 2601 Australia  
GPO Box 858, Canberra ACT 2601 Australia

---

**From:** MADSEN, Soren [<mailto:madSENS@who.int>]  
**Sent:** Tuesday, 5 November 2019 2:11 AM  
**To:** Budd, Karina <[Karina.Budd@agriculture.gov.au](mailto:Karina.Budd@agriculture.gov.au)>  
**Subject:** Fwd: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Best Regards,

Soren Madsen

(Sent from a mobile device)

Begin forwarded message:

**From:** Larry Hodges <[larryhodges@meycorp.com](mailto:larryhodges@meycorp.com)>  
**Date:** 4 November 2019 at 15:59:18 CET  
**To:** "Reichstein, Ian" <[Ian.Reichstein@agriculture.gov.au](mailto:Ian.Reichstein@agriculture.gov.au)>, "MADSEN, Soren" <[madSENS@who.int](mailto:madSENS@who.int)>

**Cc:** "VERGER, Philippe" <vergerp@who.int>, "(SPmig) Yong Zhen Yang" <yongzhen.yang@fao.org>, "Miller, David" <Miller.DavidJ@epa.gov>, "Niman, Aaron" <niman.aaron@epa.gov>, "(SPmig) Michael Doherty" <doherty.michael@epa.gov>, "Ingram, Earl" <IMCEAMAILTO-Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com>, "Furlow, Calvin" <Furlow.Calvin@epa.gov>, "Johnson, Marion" <Johnson.Marion@epa.gov>, Antoine Puech <antoinepuech@meycorp.com>

**Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR**

Dear Mr. Reichstein and Mr. Madsen,

As previously explained, AgLogic Chemical (the current and only registrant of aldicarb) is committed to supporting the existing aldicarb MRLs but we do not have access to the aldicarb studies. These studies were submitted to the US EPA by Bayer CropScience and it is unlikely that the US EPA will be able to provide the aldicarb studies to the CCPR by December 1, 2019. As it is extremely important that aldicarb not be removed from the CCPR list of pesticides we propose that the aldicarb reevaluation be rescheduled from 2020 to 2021 to allow enough time for the US EPA to submit the studies to the CCPR.

Please respond to this email and let us know how the CCPR wishes to proceed and what we can do to ensure the necessary aldicarb studies are available for review.

Best Regards,  
Larry Hodges, Ph.D.  
Director of Regulatory Affairs  
AgLogic Chemical LLC

Phone: 919-932-5800

---

**From:** Larry Hodges

**Sent:** Thursday, October 10, 2019 1:08 PM

**To:** Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; MADSEN, Soren <madsens@who.int>

**Cc:** VERGER, Philippe <vergerp@who.int>; YongZhen.Yang@fao.org;

Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>;

Doherty, Michael <Doherty.Michael@epa.gov>; Ingram, Earl ; Furlow, Calvin <Furlow.Calvin@epa.gov>;

Johnson, Marion <Johnson.Marion@epa.gov>; Antoine Puech <antoinepuech@meycorp.com>

**Subject:** Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Dear Mr. Reichstein and Mr. Madsen,

I am sending this email to advise you of the current status of the data submission for aldicarb (117) and to ask for guidance on the path forward. The attached two documents, summarized below, provide the background on our attempt to provide the CCPR with the requested aldicarb studies.

On October 24, 2018 AgLogic Chemical LLC was advised by Mr. Ian Reichstein that aldicarb was reinstated as a supported compound awaiting periodic review and would be placed as a confirmed listing for the 2020 Schedule.

We notified the CCPR that AgLogic is a generic registrant and, as allowed by US law, our aldicarb registration is supported by toxicology and residue data that were developed and submitted to the US

Environmental Protection Agency (EPA) by aldicarb's previous registrant, Bayer CropScience. We are not allowed to have copies of the actual studies that support registration and, therefore, despite our best intentions, we are not able to submit these studies to the JMPR for review.

We suggested that the since the EPA already has the supporting studies, the aldicarb reviews could be written by the EPA's residue and toxicology experts that participate in the JMPR or, alternatively, the EPA could provide the required studies to the JMPR for review by someone not from the EPA.

On May 22, 2019 AgLogic Chemical was notified by Mr. Soren Madsen that the aldicarb studies should be submitted to the JMPR for review in order to avoid possible (or perceived) conflicts of interest. We were told that the JMPR secretariat seeks to assign monographers and reviewers that have not been directly involved in recent national evaluations of the assigned compound.

We immediately contacted the EPA and asked if they could submit the aldicarb studies directly to the JMPR and EPA said that it was most appropriate to work through the Freedom of Information Act (FOIA). That determination was made based upon the requirements set forth under Section 10(g) of FIFRA, which, in part, restricts the availability of how studies/data submitted to the EPA can be released to a specific requestor. At this point the EPA Office of General Counsel contacted Bayer CropScience to get their consent to release the aldicarb studies to the JMPR.

On July 29, 2019 AgLogic Chemical was notified that Bayer decided not to consent to the EPA's direct release of aldicarb toxicology and residue studies to the JMPR. However, the EPA said they would consider if it was possible for them to provide the studies directly to the CCPR without agreement from Bayer.

On September 27, 2019 the EPA stated *"To pursue a definitive decision, CCPR would need to submit a FOIA request, identify the specific studies being requested, and identify all individuals who would have access to the requested studies. EPA would require signed Affirmations of Non-multinational Status from each of those individuals as one of the initial steps after receiving the request. I don't know if EPA would be able to make a final determination on disclosure by December 1, 2019."*

While the studies requested are in the public domain, the only way that the aldicarb studies can be provided to the CCPR is through Freedom of Information requests that are submitted to the EPA by the assigned CCPR reviewers. If this procedure is acceptable Ag Logic Chemical will identify the specific aldicarb studies that should be requested under FOIA. We will include the complete study title and MRID number so that EPA will not have any problem locating the correct studies. We will provide the list of studies to the CCPR so they can submit the FOIA requests.

As it is unlikely that this process can be completed by December 1, 2019, we propose that the aldicarb reevaluation be rescheduled from 2020 to 2021 to allow enough time for the EPA to submit the studies to the CCPR.

Please let us know how the CCPR wishes to proceed and what we can do to ensure the necessary aldicarb studies are available for review.

Best Regards,  
Larry Hodges, Ph.D.  
Director of Regulatory Affairs  
AgLogic Chemical LLC

Phone: 919-932-5800

----- IMPORTANT - This email and any attachments have been issued by the Australian Government Department of Agriculture. The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Department. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Department of Agriculture is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered -----